AUG 9 2000

K001414

R-dental Dentalerzeugnisse GmbH
Werk Winterhuder Weg 88 D-22085 Hamburg Telefon 0 40 / 22 75 76 17 Fax 0 40 / 22 75 76 18
Zertifiziert nach DIN EN ISO 9001 / DIN EN 46001 und EG-Richtlinie 93/42/EWG Anhang II (MEDCERT 0482)

10. 510(k) Summary or Statement

Summary

Gentlemen:

This submission is pursuent to paragraph 510(k) of the Federal Drug and Cosmetic Act of May, 1976 (as amended) (Title 21 USC). All informations contained herein are to be considered and treated as CONFIDENTIAL COMMERCIAL INFORMATION.

It is the intention of R-dental GmbH to manufacture KwikkModel cited above which components can be used as an silicone for making extraoral dies and models and for bite registrations.

R-dental GmbH is expanding and is marketing numerous dental products and related items worldwide.

R-dental GmbH employs Good Manufacturing Practice (GMP) pursuant and according to Title 21 CFR. R-dental GmbH is certified to DIN EN ISO 9001 and DIN EN 46001 and to the European Medical Device Directive MDD 93/42/EEC, annex II. R-dental products are generally distributed with CE-mark (if applicable).

The above cited product may be offered and marketed in the United States by Henry Schein and Patterson Dental USA, Kanada, in which case R-dental GmbH will maintain govern and control manufacturing, claims, labels, instructions for use and indications.

The cited KwikkModel R-dental GmbH manufactures contains a chemistry which is commonly found in most of the current dental impression materials.

The purpose of KwikkModel is making extraoral dies and models and bite registrations. Within the extraoral dies and models extraoral composite inlays, onlays and so on can be made.

The chemical compositions and indications of KwikkModel nature, that is KwikkModel fluid (white-grey color) and KwikkModel base (red color) are substantially equivalent to the brand MACH-2 (brown color) and BLU-MOUSSE (blue color) (by Parkell, Farmingdale, NY 11735), see enclosed copy of Parkells information.

Respectfully submitted,

Dr. Andreas Sprafke, President,
Regulatory Compliance Officer

HASPA BLZ 200 505 50 Kto.-Nr. 1254 12 55 50
Vereins- und Westbank AG BLZ 200 300 00 Kto.-Nr. 38 66 80
Ust-IdNr. DE 177 63 08 20

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HR B Hamburg 59502 Geschäftsführer Dr. Andreas Sprafke

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Dr. Andreas Sprafke
President
R-dental Dentalerzeugnisse GmbH
Winterhuder Weg 88
D-22085 Hamburg
GERMANY

Re: K001414
Trade Name: Kwikkmodel
Regulatory Class: II
Product Code: ELW
Dated: July 13, 2000
Received: July 24, 2000

Dear Dr. Sprafke:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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9. Statement of Indication for Use

Statement

510(k) Number (if Known): -

Device name: **KwikkModel**

Indication for Use (see appendix 2):

KwikkModel nature, consists of KwikkModel fluid and KwikkModel base, are addition curing silicones on vinylpolysiloxane base for making extraoral dies and silicone models of teeth. KwikkModel nature can also be used for bite registrations.

MSDS (see appendix 3):

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K001414

Prescription Use: ✓ or Over-The-Counter Use

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